

JUN - 6 2001



K003983
Stockert GmbH

510(k) Summary

December 22nd, 2000

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This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Contact: Dominika Schuler, Quality Assurance Manager

Trade Name: Stimuplex HNS-11

Common Name: Battery powered peripheral Nerve Stimulator

Classification Name:

Anesthesiology Devices, Class II, 73 BXN
Battery Powered Nerve Stimulator
21 CFR 868.2775

Predicate Device: Fisher & Paykel, NS272 Nerve Stimulator / Locator
K953205

The Nerve stimulator Stimuplex HNS-11 is a battery powered peripheral nerve stimulator for localization of nerve fibers in the tissue. During the operation the operating physician holds a stimulation cannula in his right hand. Simultaneous the operation of the device happens with his left hand. The physician can hold the device with the left hand and simultaneous alter the stimulation amplitude at the amplitude controller.

The technical data of the device are:

Battery:	9 Volt alkaline
Display:	one numeric LCD 10 LED's for status display
Operation:	Adjustment-knob to switch on the device and to adjust the wanted stimulation current. 5 control buttons to switch between the operating modes.
Power consumption:	3.3 mA
Stimulation current :	max. 5mA _{app} / 0Ω - 12 kΩ
Stimulation voltage :	max. 65 V _{pp}
Stimulation frequency :	1 Hz / 2 Hz
Measuring tolerance:	Adjustment control display = 3% (set point) Flowing current display = 2% (actual value) based on set mA max values (5mA or 1 mA)

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Weight: 0.25 kg (with battery)

The configuration of the electrode connection is realized with a 5 pin plug connection system, which ensures correct polarity of the electrode at all times. The Stimuplex HNS-11 generates negative, current-stabilized square pulses with selectable frequency, selectable pulse width and continuously adjustable stimulation current. The pulse is shaped at both slopes by extremely fast active pulse drivers. An output amplifier specially designed for this application has an extraordinarily wide dynamic range and produces reproducible settings even below 0.1 mA. The stimulation frequency and the pulse width can be varied for different applications. The Stimuplex HNS-11 nerve stimulator offers the facility for selecting a frequency of either 1 Hz or 2 Hz can be chosen together with pulse widths of 0.1 ms, 0.3 ms or 1.0 ms. When the Stimuplex HNS-11 is switched off, all set parameters remain stored. By a button the battery voltage can be display for the duration of the button actuation.

The intended use is a peripheral nerve stimulator to test the level of pharmacological effect of anesthetic drugs and gases to the patient and/or as a nerve locator for the verification of needle placement for the application of local anesthetics. This device can be used wherever peripheral anesthesia is normally applied (i.e. physicians office or hospital). There are no known contraindications for the use of this device on any patient population.

The general technological characteristics of the Stimuplex HNS-11 are generally equivalent in materials, form and intended use to the Fisher & Paykel NS272 Peripheral Nerve Stimulator. Differences between the Stimuplex HNS-11 and the predicate device consist in the additional functions, like surface stimulation and others, of the predicate device. The Stimuplex HNS-11 is high specific for it's intended use in the anaesthesiology. The differences don't affect safety and effectiveness for the intended use.

All finished products are tested and must meet all required release specifications before distribution. The array of testing required for release include, but are not limited to: physical testing, visual examination (in process and finished product). The physical testing is defined by Quality Control Test Procedure documents. These tests are established testing procedures and parameters which conform to the product design specifications. The testing instruction records for each of the individually required procedures are approved, released, distributed and revised in accordance with document control GMP's.

signed: 
Dominika Schuler, Quality Assurance Manager
Stockert GmbH

date: Dec. 22nd, 2000



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Dominika Schuler
Quality Assurance Manager
Stockert GmbH
Boetzinger Strabe 72
D-79111 Freiburg
GERMANY

Re: K003983

Trade Name: Stimuplex HNS-11
Regulation Number: 868.2775
Regulatory Class: II (two)
Product Code: BXN
Dated: March 21, 2001
Received: March 23, 2001

Dear Ms. Schuler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

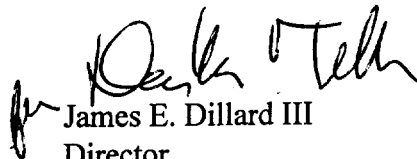
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "James E. Dillard III", is written over the typed name.

James E. Dillard III

Director

Division of Cardiovascular
and Respiratory Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Statement of Intended Use

Device: Peripheral Nerve Stimulator

Name: Stimuplex HNS-11

Indications for Use:

A peripheral nerve stimulator to test the level of pharmacological effects of anesthetic drugs and gases to the patient and/or as a nerve locator for the verification of needle placement for the application of local anesthetics. This device can be used wherever peripheral anesthesia is normally applied (i.e. physicians office or hospital). There are no known contraindications for the use of this device on any patient population.


Division of Cardiovascular & Respiratory Devices
510(k) Number K004983

Prescription Use Only